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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,393

11/21/2006

Naoko Horikoshi

4439-4045

3674

27123

7590

01/27/2010

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

01/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Shopkins@Lockelord.com  
OWalker@Lockelord.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,393	<b>Applicant(s)</b> HORIKOSHI ET AL.	
	<b>Examiner</b> Khatol S. Shahnian-Shah	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

1. Applicants' amendments of 10/29/2009 are acknowledged. Claims 1, 11 and 13 have been amended.

***Status of Claims***

2. Claims 1-18 are pending in this application. Claims 5-8 and 17 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 1-4, 9-16 and 18 are under consideration.

***Objections Withdrawn***

3. Objection to the drawing made in paragraph 4 of the office action mailed 7/30/2009 is withdrawn in view Applicants' amendments of 10/29/2009.
4. Objection to the specification made in paragraph 6 of the office action mailed 7/30/2009 is withdrawn in view Applicants' amendments of 10/29/2009.
5. Objection to the abstract made in paragraph 7 of the office action mailed 7/30/2009 is withdrawn in view Applicants' amendments of 10/29/2009.
6. Objection to the claims 11 and 13 made in paragraph 9 of the office action mailed 7/30/2009 is withdrawn in view Applicants' amendments of 10/29/2009.

***Rejections Withdrawn***

7. Rejection of claims 1-4, 9-16 and 18 under 35 U.S.C. 112 second paragraph, made in paragraph 11 of the office action mailed 7/30/2009 is withdrawn in view of applicants' amendments of 10/29/2009.
8. Rejection of claims 1, 2, 3, 4, 11, 15, 16 18 under 35 U.S.C. 102 (b), made in paragraph 13 of the office action mailed 7/30/2009 is withdrawn in view of applicants' amendments of 10/29/2009.
9. Rejection of claims 1, 11 and 18 under 35 U.S.C. 102 (b), made in paragraph 14 of the office action mailed 7/30/2009 is withdrawn in view of applicants' amendments of 10/29/2009.
10. Rejection of claims 1-4, 9-16 and 18 under 35 U.S.C. 103(a), made in paragraph 16 of the office action mailed 7/30/2009 is withdrawn in view of applicants' amendments of 10/29/2009.

***New Rejections***  
***Claim Rejections - 35 USC § 103***

**11.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**12.** Claim 1-4, 9-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aznar et al. ( Systematic and Applied Microbiology, vol.25, pp. 109-119, 2002) in view Brasher et al. ( Current Microbiology vol.37, pp. 101-107, 1998) all prior art of record applicants' 1449.

The claims are drawn to a method of multiple microorganism detection which is a method for detecting two or more microorganisms having different properties in foods, with high sensitivity comparable or even superior to official methods, by amplifying a plurality of target genes with a single PCR reaction tube and analyzing the same, comprising the following steps:(A) a step for extracting DNA of the target microorganisms to be detected, by treating at least with a lytic enzyme and/or bacteriocin having lytic activity, a surfactant and a protein denaturant; and (B) a step for performing Multiplex PCR by mixing a primer specific to the target microorganisms to be detected.

Aznar et al. teach a total of nine pairs of primers, seven previously published and two newly developed, have been assayed for PCR detection of *Listeria monocytogenes*

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in food. They have been tested for specificity on a total of 72 strains including reference and food isolates belonging to *L. monocytogenes* and other species in the genus. (See abstract). Chromosomal DNA was extracted by the guanidium thio-cyanate i.e. a protein denaturant (see page 110 DNA isolation). Aznar et al. teach detecting two or more microorganisms having different properties (see table 1). Aznar et al. SEQ ID NO: 5 and SEQ ID NO: 6 (see table 2). Aznar et al. teach edible meat and processed meat products (see table 1). Aznar et al. teach culture enrichment after 24 hour of culture (see page 110 growth conditions). The prior teaches the above claims. Aznar et al. do not teach certain limitations such pH, medium components or chemicals used to lyse the microorganism before DNA extraction.

Brasher et al. teach a sensitive and rapid method for detecting Salmonella, Vibrio, Escherichia coli and other bacteria which cause food poisoning was developed. In this method, an oligonucleotide primer for five specific genes for each bacterium is used to amplify the five target genes through a single PCR, and it is suggested that this method can be applied to monitoring of pathogens as it is more sensitive and faster than detection using ordinary cultures (see abstract). Brasher et al. teach Multiplex PCR amplification of *uidA*, *cth*, *invA*, *ctx*, and *tl* genes was developed enabling simultaneous detection in shellfish of *Escherichia coli*, an indicator of fecal contamination and microbial pathogens, *Salmonella typhimurium*, *Vibrio vulnificus*, *V. cholerae*, and *V. parahaemolyticus*, respectively. Each of the five pairs of oligonucleotide primers was found to support PCR amplifications of only its targeted gene (see abstract). Brasher et al. teach a lytic enzyme (proteinase K) and depositing DNA by alcohol precipitation (see material and methods, page 102).

It would be prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Aznar et al. and Brasher et al. to obtain the claimed invention. One of ordinary skill in the art would have been motivated to by teaching of Aznar et al. to optimize the culture media and pH to obtain the best results for a Multiplex PCR assay. One of ordinary skill in the art would have been also

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motivated to by teaching of Brasher et al. using a lytic enzyme in the extraction of DNA in the method.

***Conclusion***

**13** No claims are allowed.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thur-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on (571)-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/  
Examiner, Art Unit 1645  
1/15/2009

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645